

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

Date Prepared:

August 7, 2005

Submitter's Information:

Soring GmbH Medizintechnik
 Justus-v.Liebig 10
 25451 Quickborn
 Germany

Telephone: 49 4106-5055

Fax: 49 4106-5271

Email: info@soering.com

Trade Name, Common Name, Classification:

Trade name: Soring GmbH, Sonoca™-Lipo
 Common name: Instrument, Ultrasonic Surgical
 Classification name: General and Plastic Surgery

Predicate Device:

DEVICE CLASSIFICATION NAME	<u>PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)</u>	<u>SYSTEM, SUCTION, LIPOPLASTY</u>
REGULATION NUMBER	<u>878.4780</u>	<u>878.5040</u>
510(K) NUMBER	K992026	K041058
DEVICE NAME	SORING GMBH, SONOCA 300	MISONIX INC. LYSONIX 2000/3000 ULTRASONIC SURGICA
APPLICANT	SORING GMBH	<u>MISONIX, INC.</u>
PRODUCT CODE	BTA AND LFL	MUU
DECISION DATE	09/23/1999	05/17/2004

Device Description:

SONOCA Lipo™ is a modified version of the SONOCA 300 cleared by FDA under K992026 and can be used in two ways:

1. As an ultrasonic dissector / aspirator as in the SONOCA 300 to cut, irrigate, and suction at the surgical site and
2. As an alternative to conventional Lipectomy because it is a combination of a standard Lipectomy suction device and an Ultrasound assisted Lipectomy for the selective dissection of human fatty tissue.

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The SONOCA Lipo™ is not an alternative to conventional surgery but a supplementary tool which provides an advantage for the selective dissection of human tissue.

The advantage of the SONOCA is that the tissue selectivity of the ultrasonically induced cutting effect limits the spectrum to organs with a large proportion of parenchyma in which sustentacular tissue is only minimally developed.

During the use of an ultrasonic dissector, power is transmitted from a longitudinal vibrating probe tip in the contact zone to tissue. The probe with the integrated aspiration/irrigation function collects the cell and tissue fragments.

The SONOCA Lipo™ can be trolley mounted or a desktop unit consisting of an ultrasonic generator, an infiltration pump and an aspiration pump. The modular build of the electronic components allow the unit to function at a high capacity, totally free of electronic maintenance.

Indications for Use:

The SONOCA Lipo™ is an instrument indicated for selected ultrasound dissection, liquefaction, emulsifying and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery, and Gynecological Surgery applications. It is also indicated for the liquefaction and aspiration of localized subcutaneous fatty tissue for aesthetic body contouring. Typical users of this system are trained medical professionals.

Performance Data:

The subject and predicate devices have been designed and tested to pass the following Voluntary Standards: UL 260 1-1 Medical Electrical Equipment, Part 1: General Requirements for Safety EN 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety EN 60601-1-2:1993 Electromagnetic Compatibility and FCC Part 18 EMC Requirement. The subject device complies with IEC 950 – Safety of Information Technology Equipment, CISPR 22, class A – Electromagnetic Compatibility, IEC-801-2, IEC-801-3 – Electromagnetic Compatibility, IEEE 1003.1 – General Electrical Safety for medical devices, IEC 601-1 –Electrical Safety for medical devices using RF-power, IEC 601-2-2– Ultrasonic surgical devices, DIN EN 61847

Conclusion:

Similar to the predicate devices, the SONOCA Lipo™ does not control any life sustaining functions or services. The new device and the predicate devices share the same conformance to performance standards and both function as Ultrasonic Dissectors. Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.



OCT 7 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Soring GmbH Medizintechnik
c/o Mr. Carl Alletto
1600 Manchester Way
Corinth, Texas 76210

Re: K052183
Trade/Device Name: Soring, SONOCA-Lipo
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: August 7, 2005
Received: August 15, 2005

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

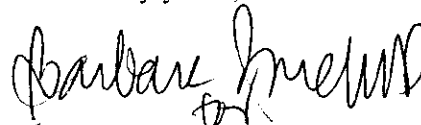
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2-Mr. Carl Alletto

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a horizontal line.

Mark N. Melkerson

Acting Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Soring, SONOCA-Lipo

Indications for Use:

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Typical users of this system are trained medical professionals.

Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

Barbara Buchholz for MIM
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052183